EXHIBIT B

Exhibit 20

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
CLARKSBURG DIVISION

REGENERON PHARMACEUTICALS, INC., Plaintiff, v. MYLAN PHARMACEUTICALS INC., Defendant.	Case No. 1:22-cv-00061-TSK **JURY TRIAL DEMANDED** [redacted]

FINAL INFRINGEMENT CONTENTIONS OF PLAINTIFF REGENERON PHARMACEUTICALS, INC. FOR U.S. PATENT NO. 11,253,572

Plaintiff Regeneron Pharmaceuticals, Inc. ("Regeneron") discloses the following final infringement contentions regarding U.S. Patent No. 11,253,572 ("Yancopoulos '572") to Defendant Mylan Pharmaceuticals Inc. ("Mylan"). Regeneron is presently asserting claims 1-23 and 25–30 from Yancopoulos '572.

Regeneron's infringement contentions are based on the information currently available to, and known by, Regeneron. Regeneron has only received a limited set of documents from Mylan and has not yet received samples. Regeneron has also not yet obtained complete discovery from third parties that may have information relevant to this patent. Regeneron has also not yet obtained deposition testimony from a number of Mylan witnesses who may have knowledge relevant to this patent. Furthermore, the Court has not yet construed any of the asserted claims of this patent. As a result, Regeneron reserves the right to modify, amend, or otherwise supplement these infringement contentions as the pre-trial phase of the litigation proceeds and as additional information comes to light, and as provided in the case Scheduling

Order, the Federal Rules of Civil Procedure, and the Local Rules of the Northern District of West Virginia.

This claim chart is provided without prejudice to Regeneron's right to introduce expert opinions and demonstratives as expert discovery progress, and to produce and introduce at trial all evidence, whenever discovered, related to the proof of currently known and subsequently discovered facts. In addition, the division of each claim into individual limitations below is for convenience only and is without prejudice to Regeneron's right to argue for a different division at a later date.

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The commercial marketing of Mylan's M710 will induce the infringement of claims 1–23 and 25–30 of U.S. Patent No. 11,253,572 ("the '572 Patent" or "Yancopoulos '572") pursuant to 35 U.S.C. §§ 271(b) and (e). Mylan's marketing of M710 as a biosimilar to and/or interchangeable with Eylea® will encourage and induce physicians to take actions that will directly infringe the claims of the '572 Patent and evidences Mylan's intent for such infringement to occur. As a result of Mylan's marketing of M710 as a biosimilar to and/or interchangeable with Eylea®, including with the package insert Mylan has produced to Regeneron at MYL-AFL-BLA1079688, acts of direct infringement will occur. Mylan is liable for induced infringement.

For the reasons set forth in the below chart, administration of M710 in accordance with Mylan's proposed labeling for M710, *see, e.g.*, MYL-AFL-BLA1079688, will directly infringe the identified claims of the '572 Patent. Mylan's aBLA, including the proposed labeling, will encourage and induce physicians to directly infringe the claims of the '572 Patent. Because Mylan's BLA for M710, including the proposed labeling, encourages and induces such infringing actions, Mylan intends infringement to occur and is liable for induced infringement.

The chart below details how Mylan's proposed labeling for M710 directs physicians to perform the claimed methods of the '572 Patent. To the extent unasserted claims are included in the chart, those claims are provided to demonstrate that Mylan's marketing o M710 directs physicians to perform the limitations of claims from which asserted claims depend.

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'572 Patent Claims	**M710**
(1pre) 1. A method of treating an angiogenic eye disorder in a patient in need thereof comprising	**Mylan's proposed labeling directs physicians to treat angiogenic eye disorders by administering aflibercept.** *See, e.g.*, MYL-AFL-BLA1079688 at Highlights of Prescribing Information (directing administration of aflibercept to treat Wet

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'572 Patent Claims	**M710**
	AMD, RVO, DR, and DME); MYL-AFL-BLA1079688 at -1079700, at section 12.1 ("Vascular endothelial growth factor-A (VEGF-A) and placental growth factor (PlGF) are members of the VEGF family of angiogenic factors that can act as mitogenic, chemotactic, and vascular permeability factors for endothelial cells. VEGF acts via two receptor tyrosine kinases, VEGFR-1 and VEGFR-2, present on the surface of endothelial cells. PlGF binds only to VEGFR-1, which is also present on the surface of leucocytes. Activation of these receptors by VEGF-A can result in neovascularization and vascular permeability. Aflibercept acts as a soluble decoy receptor that binds VEGF-A and PlGF, and thereby can inhibit the binding and activation of these cognate VEGF receptors."). **In accordance with Mylan's proposed labeling, physicians will administer aflibercept to treat angiogenic eye disorders.** *See, e.g.*, MYL-AFL-BLA1079688 at Highlights of Prescribing Information (directing administration of aflibercept to treat Wet AMD, RVO, DR, and DME); MYL-AFL-BLA1079688 at -1079700, at section 12.1 ("Vascular endothelial growth factor-A (VEGF-A) and placental growth factor (PlGF) are members of the VEGF family of angiogenic factors that can act as mitogenic, chemotactic, and vascular permeability factors for endothelial cells. VEGF acts via two receptor tyrosine kinases, VEGFR-1 and VEGFR-2, present on the surface of endothelial cells. PlGF binds only to VEGFR-1, which is also present on the surface of leucocytes. Activation of these receptors by VEGF-A can result in neovascularization and vascular permeability. Aflibercept acts as a soluble decoy receptor that binds VEGF-A and PlGF, and thereby can inhibit the binding and activation of these cognate VEGF receptors.").
(1a) sequentially administering to the patient by intravitreal injection a single initial dose of 2 mg of aflibercept, followed by one or more secondary doses of 2 mg of aflibercept, followed by one or more tertiary doses of 2 mg of aflibercept;	**Mylan's proposed labeling directs physicians to treat wet AMD, DME, and DR—angiogenic eye disorders—by administering a single initial dose of 2 mg of aflibercept, followed by one or more secondary doses of 2 mg of aflibercept, followed by one or more tertiary doses of 2 mg of aflibercept.** *See, e.g.*, MYL-AFL-BLA1079688 at Highlights of Prescribing Information (directing that, for the treatment of wet AMD, "[t]he recommended dose for YESAFILI is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks

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'572 Patent Claims	**M710**
	(approximately every 28 days, monthly) for the first 3 months, followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months)," and directing that, for the treatment of DME and DR, "[t]he recommended dose for YESAFILI is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 5 injections followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months)"). **In accordance with Mylan's proposed labeling, physicians will treat wet AMD, DME, DR—angiogenic eye disorders—by administering a single initial dose of 2 mg of aflibercept, followed by one or more secondary doses of 2 mg of aflibercept, followed by one or more tertiary doses of 2 mg of aflibercept.** *See, e.g.*, MYL-AFL-BLA1079688 at Highlights of Prescribing Information (directing that, for the treatment of wet AMD, "[t]he recommended dose for YESAFILI is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 3 months, followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months)," and directing that, for the treatment of DME and DR, "[t]he recommended dose for YESAFILI is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 5 injections followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months)").
(1b) wherein each secondary dose is administered approximately 4 weeks following the immediately preceding dose; and	**Mylan's proposed labeling directs physicians to administer each secondary dose of 2 mg of aflibercept approximately 4 weeks following the immediately preceding dose.** *See, e.g.*, MYL-AFL-BLA1079688 at Highlights of Prescribing Information (directing that, for the treatment of wet AMD, "[t]he recommended dose for YESAFILI is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 3 months, followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months)," and directing that, for the treatment of DME and DR, "[t]he recommended dose for YESAFILI is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 5

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	injections followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months)"). **In accordance with Mylan's proposed labeling, physicians will treat angiogenic eye disorders by administering each secondary dose of 2 mg of aflibercept approximately 4 weeks following the immediately preceding dose.** *See, e.g.*, MYL-AFL-BLA1079688 at Highlights of Prescribing Information (directing that, for the treatment of wet AMD, "[t]he recommended dose for YESAFILI is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 3 months, followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months)," and directing that, for the treatment of DME and DR, "[t]he recommended dose for YESAFILI is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 5 injections followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months)").
(1c) wherein each tertiary dose is administered approximately 8 weeks following the immediately preceding dose;	**Following administration of the secondary doses, as directed by Mylan's proposed labeling for the treatment of wet AMD, DME, and DR (i.e., angiogenic eye disorders), for example, Mylan's proposed labeling directs physicians to administer each tertiary dose of 2 mg (0.05 mL) of aflibercept approximately once every 8 weeks or once every 2 months to treat the angiogenic eye disorder.** *See, e.g.*, MYL-AFL-BLA1079688 at Highlights of Prescribing Information ("The recommended dose for YESAFILI is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 3 months, followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months)."); MYL-AFL-BLA1079688 at -1079689, at section 2.2 ("The recommended dose for YESAFILI is 2 mg (0.05 mL or 50 microliters) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 12 weeks (3 months), followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months)."); MYL-AFL-BLA1079688 at -1079689, at Section 2.4 ("The recommended dose for YESAFILI is 2 mg (0.05 mL or 50 microliters) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 5

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	injections, followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months)."); MYL-AFL-BLA1079688 at -1079690, at Section 2.5 ("The recommended dose for YESAFILI is 2 mg (0.05 mL or 50 microliters) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 5 injections, followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months)." **In accordance with Mylan's proposed labeling, following administration of secondary doses of 2 mg of aflibercept, physicians will administer each tertiary dose of 2 mg (0.05 mL) of aflibercept approximately once every 8 weeks or once every 2 months to treat the angiogenic eye disorder.** *See, e.g.*, MYL-AFL-BLA1079688 at Highlights of Prescribing Information ("The recommended dose for YESAFILI is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 3 months, followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months)."); MYL-AFL-BLA1079688 at -1079689, at section 2.2 ("The recommended dose for YESAFILI is 2 mg (0.05 mL or 50 microliters) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 12 weeks (3 months), followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months)."); MYL-AFL-BLA1079688 at -1079689, at Section 2.4 ("The recommended dose for YESAFILI is 2 mg (0.05 mL or 50 microliters) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 5 injections, followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months)."); MYL-AFL-BLA1079688 at -1079690, at Section 2.5 ("The recommended dose for YESAFILI is 2 mg (0.05 mL or 50 microliters) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 5 injections, followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months)."
(1d) wherein the patient achieves a gain in visual acuity within 52 weeks following the initial dose.	**Mylan's proposed labeling directs physicians to administer aflibercept to treat angiogenic eye disorders such that a patient will achieve a gain in visual acuity within 52 weeks after the initial dose.** *See, e.g.*, MYL-AFL-BLA1079688 at -1079702–1079704, at section 14.1 ("In both studies, the primary efficacy endpoint

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	was the proportion of patients who maintained vision, defined as losing fewer than 15 letters of visual acuity at week 52 compared to baseline. Both aflibercept 2Q8 and aflibercept 2Q4 groups were shown to have efficacy that was clinically equivalent to the ranibizumab 0.5 mg Q4 group in year 1."); MYL-AFL-BLA1079688 at -1079704–1079706, at section 14.2 ("In both studies, the primary efficacy endpoint was the proportion of patients who gained at least 15 letters in BCVA compared to baseline. At week 24, the aflibercept 2 mg Q4 group was superior to the control group for the primary endpoint."); MYL-AFL-BLA1079688 at -1079706–1079707, at section 14.3 ("In the VIBRANT study, the primary efficacy endpoint was the proportion of patients who gained at least 15 letters in BCVA at week 24 compared to baseline."); MYL-AFL-BLA1079688 at -1079708–1079710, at section 14.4 ("In both studies, the primary efficacy endpoint was the mean change from baseline in BCVA at week 52 as measured by ETDRS letter score."); MYL-AFL-BLA1079688 at -1079710–1079713, at section 14.5 ("The primary efficacy endpoint was the proportion of patients who improved by ≥2 steps on the DRSS from baseline to week 24 in the combined aflibercept groups and at week 52 in the 2Q16 and 2Q8 groups individually versus sham."); MYL-AFL0006405; MYL-AFL0004715; Brown et al., *Evaluation of Intravitreal Aflibercept for the Treatment of Severe Nonproliferative Diabetic Retinopathy: Results from the Panorama Clinical Trial*, Jama Opthalmol. 2021:139(9):946-655 ("Brown 2021"). **In accordance with Mylan's proposed labeling, physicians will treat angiogenic eye disorders by administering aflibercept such that a patient will achieve a gain in visual acuity within 52 weeks after the initial dose.** *See, e.g.*, MYL-AFL-BLA1079688 at -1079702–1079704, at section 14.1 ("In both studies, the primary efficacy endpoint was the proportion of patients who maintained vision, defined as losing fewer than 15 letters of visual acuity at week 52 compared to baseline. Both aflibercept 2Q8 and aflibercept 2Q4 groups were shown to have efficacy that was clinically equivalent to the ranibizumab 0.5 mg Q4 group in year 1."); MYL-AFL-BLA1079688 at -1079704–1079706, at section 14.2 ("In both studies, the primary efficacy endpoint was the proportion of patients who gained at least 15 letters in BCVA

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	compared to baseline. At week 24, the aflibercept 2 mg Q4 group was superior to the control group for the primary endpoint."); MYL-AFL-BLA1079688 at -1079706–1079707, at section 14.3 ("In the VIBRANT study, the primary efficacy endpoint was the proportion of patients who gained at least 15 letters in BCVA at week 24 compared to baseline."); MYL-AFL-BLA1079688 at -1079708–1079710, at section 14.4 ("In both studies, the primary efficacy endpoint was the mean change from baseline in BCVA at week 52 as measured by ETDRS letter score."); MYL-AFL-BLA1079688 at -1079710–1079713, at section 14.5 ("The primary efficacy endpoint was the proportion of patients who improved by ≥2 steps on the DRSS from baseline to week 24 in the combined aflibercept groups and at week 52 in the 2Q16 and 2Q8 groups individually versus sham."); MYL-AFL0006405; MYL-AFL0004715; Brown 2021.
2. The method of claim 1 wherein the patient achieves a gain in Best Corrected Visual Acuity (BCVA) according to Early Treatment Diabetic Retinopathy Study (ETDRS) letter score.	**Administration of aflibercept in accordance with Mylan's proposed labeling practices claim 1 as set forth above.** **Mylan's proposed labeling directs physicians to administer aflibercept to treat wet AMD, DME, and/or DR (i.e., angiogenic eye disorders) such that a patient will achieve a gain in Best Corrected Visual Acuity (BCVA) according to Early Treatment Diabetic Retinopathy Study (ETDRS) letter score.** *See, e.g.*, MYL-AFL-BLA1079688 at -1079702–1079704, at section 14.1 ("The safety and efficacy of aflibercept were assessed in two randomized, multi-center, double-masked, active-controlled studies in patients with wet AMD. A total of 2412 patients were treated and evaluable for efficacy (1817 with aflibercept) in the two studies (VIEW1 and VIEW2). In each study, up to week 52, patients were randomly assigned in a 1:1:1:1 ratio to 1 of 4 dosing regimens: 1) aflibercept administered 2 mg every 8 weeks following 3 initial monthly doses (aflibercept 2Q8); 2) aflibercept administered 2 mg every 4 weeks (aflibercept 2Q4); 3) aflibercept 0.5 mg administered every 4 weeks (aflibercept 0.5Q4); and 4) ranibizumab administered 0.5 mg every 4 weeks (ranibizumab 0.5 mg Q4)."); MYL-AFL-BLA1079688 at -1079702–1079703, at section 14.1, tbl. 4 (showing that 31% (VIEW1 and VIEW2) of wet AMD patients treated with three monthly 2 mg doses of

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	aflibercept followed by 2 mg doses administered once every 8 weeks gained at least 15 letters of vision (i.e., BCVA score)); MYL-AFL-BLA1079688 at -1079708–1079710, at Section 14.4; MYL-AFL0004715; MYL-AFL-BLA1079688 at -1079710–1079713, at Section 14.5. **In accordance with Mylan's proposed labeling, physicians will treat angiogenic eye disorders by using the method of claim 1, resulting in a patient achieving a gain in Best Corrected Visual Acuity (BCVA) according to Early Treatment Diabetic Retinopathy Study (ETDRS) letter score.** *See, e.g.*, MYL-AFL-BLA1079688 at -1079702–1079704, at section 14.1 ("The safety and efficacy of aflibercept were assessed in two randomized, multi-center, double-masked, active-controlled studies in patients with wet AMD. A total of 2412 patients were treated and evaluable for efficacy (1817 with aflibercept) in the two studies (VIEW1 and VIEW2). In each study, up to week 52, patients were randomly assigned in a 1:1:1:1 ratio to 1 of 4 dosing regimens: 1) aflibercept administered 2 mg every 8 weeks following 3 initial monthly doses (aflibercept 2Q8); 2) aflibercept administered 2 mg every 4 weeks (aflibercept 2Q4); 3) aflibercept 0.5 mg administered every 4 weeks (aflibercept 0.5Q4); and 4) ranibizumab administered 0.5 mg every 4 weeks (ranibizumab 0.5 mg Q4)."); MYL-AFL-BLA1079688 at -1079702–1079703, at section 14.1, tbl. 4 (showing that 31% (VIEW1 and VIEW2) of wet AMD patients treated with three monthly 2 mg doses of aflibercept followed by 2 mg doses administered once every 8 weeks gained at least 15 letters of vision (i.e., BCVA score)); MYL-AFL-BLA1079688 at -1079708–1079710, at Section 14.4; MYL-AFL-BLA1079688 at -1079710–1079713, at Section 14.5; MYL-AFL0006405; MYL-AFL0004715; Brown 2021.
3. The method of claim 2 wherein the patient gains at least 7 letters Best Corrected Visual Acuity (BCVA) according to Early Treatment Diabetic	**Administration of aflibercept in accordance with Mylan's proposed labeling practices claim 2 as set forth above.** **Mylan's proposed labeling directs physicians to administer aflibercept to treat wet AMD such that a patient will gain at least 7 letters Best Corrected Visual Acuity (BCVA)**

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Retinopathy Study (ETDRS) letter score.	**according to Early Treatment Diabetic Retinopathy Study (ETDRS) letter score.** *See, e.g.*, MYL-AFL-BLA1079688 at -1079702–1079704, at section 14.1 ("The safety and efficacy of aflibercept were assessed in two randomized, multi-center, double-masked, active-controlled studies in patients with wet AMD. A total of 2412 patients were treated and evaluable for efficacy (1817 with aflibercept) in the two studies (VIEW1 and VIEW2). In each study, up to week 52, patients were randomly assigned in a 1:1:1:1 ratio to 1 of 4 dosing regimens: 1) aflibercept administered 2 mg every 8 weeks following 3 initial monthly doses (aflibercept 2Q8); 2) aflibercept administered 2 mg every 4 weeks (aflibercept 2Q4); 3) aflibercept 0.5 mg administered every 4 weeks (aflibercept 0.5Q4); and 4) ranibizumab administered 0.5 mg every 4 weeks (ranibizumab 0.5 mg Q4)."); MYL-AFL-BLA1079688 at -1079702–1079703, at section 14.1, tbl. 4 (showing that 31% (VIEW1 and VIEW2) of wet AMD patients treated with three monthly 2 mg doses of aflibercept followed by 2 mg doses administered once every 8 weeks gained at least 15 letters of vision (i.e., BCVA score)); MYL-AFL-BLA1079688 at -1079708–1079710, at Section 14.4; MYL-AFL-BLA1079688 at -1079710–1079713, at Section 14.5; MYL-AFL0006405; MYL-AFL0004715; Brown 2021. **In accordance with Mylan's proposed labeling, physicians will treat angiogenic eye disorders by using the method of claim 2, resulting in a patient gaining at least 7 letters Best Corrected Visual Acuity (BCVA) according to Early Treatment Diabetic Retinopathy Study (ETDRS) letter score.** *See, e.g.*, MYL-AFL-BLA1079688 at -1079702–1079704, at section 14.1 ("The safety and efficacy of aflibercept were assessed in two randomized, multi-center, double-masked, active-controlled studies in patients with wet AMD. A total of 2412 patients were treated and evaluable for efficacy (1817 with aflibercept) in the two studies (VIEW1 and VIEW2). In each study, up to week 52, patients were randomly assigned in a 1:1:1:1 ratio to 1 of 4 dosing regimens: 1) aflibercept administered 2 mg every 8 weeks following 3 initial monthly doses (aflibercept 2Q8); 2) aflibercept administered 2 mg every

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	4 weeks (aflibercept 2Q4); 3) aflibercept 0.5 mg administered every 4 weeks (aflibercept 0.5Q4); and 4) ranibizumab administered 0.5 mg every 4 weeks (ranibizumab 0.5 mg Q4)."); MYL-AFL-BLA1079688 at -1079702–1079703, at section 14.1, tbl. 4 (showing that 31% (VIEW1 and VIEW2) of wet AMD patients treated with three monthly 2 mg doses of aflibercept followed by 2 mg doses administered once every 8 weeks gained at least 15 letters of vision (i.e., BCVA score)); MYL-AFL-BLA1079688 at -1079708–1079710, at Section 14.4; MYL-AFL-BLA1079688 at -1079710–1079713, at Section 14.5; MYL-AFL0006405; MYL-AFL0004715; Brown 2021.
4. The method of claim 3 wherein the patient achieves the gain in visual acuity within 24 weeks following the initial dose.	**Administration of aflibercept in accordance with Mylan's proposed labeling practices claim 3 as set forth above.** **Mylan's proposed labeling directs physicians to administer aflibercept to treat angiogenic eye disorders such that a patient will achieve the gain in visual acuity within 24 weeks after the initial dose.** *See, e.g.*, MYL-AFL-BLA1079688 at -1079704–1079706, at section 14.2 ("In both studies, the primary efficacy endpoint was the proportion of patients who gained at least 15 letters in BCVA compared to baseline. At week 24, the aflibercept 2 mg Q4 group was superior to the control group for the primary endpoint."); MYL-AFL-BLA1079688 at -1079706–1079707, at section 14.3 ("In the VIBRANT study, the primary efficacy endpoint was the proportion of patients who gained at least 15 letters in BCVA at week 24 compared to baseline."); MYL-AFL-BLA1079688 at -1079710–1079713, at section 14.5 ("The primary efficacy endpoint was the proportion of patients who improved by ≥2 steps on the DRSS from baseline to week 24 in the combined aflibercept groups and at week 52 in the 2Q16 and 2Q8 groups individually versus sham."); MYL-AFL-BLA1079688 at -1079702–1079704, at Section 14.1; MYL-AFL-BLA1079688 at -1079708–1079710, at Section 14.4; MYL-AFL0004715; MYL-AFL0006405; MYL-AFL0004715; Brown 2021. **In accordance with Mylan's proposed labeling, physicians will treat angiogenic eye disorders by administering**

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	aflibercept such that a patient will achieve the gain in visual acuity within 4 weeks after the initial dose. *See, e.g.*, MYL-AFL-BLA1079688 at -1079704–1079706, at section 14.2 ("In both studies, the primary efficacy endpoint was the proportion of patients who gained at least 15 letters in BCVA compared to baseline. At week 24, the aflibercept 2 mg Q4 group was superior to the control group for the primary endpoint."); MYL-AFL-BLA1079688 at -1079706–1079707, at section 14.3 ("In the VIBRANT study, the primary efficacy endpoint was the proportion of patients who gained at least 15 letters in BCVA at week 24 compared to baseline."); MYL-AFL-BLA1079688 at -1079710–1079713, at section 14.5 ("The primary efficacy endpoint was the proportion of patients who improved by ≥2 steps on the DRSS from baseline to week 24 in the combined aflibercept groups and at week 52 in the 2Q16 and 2Q8 groups individually versus sham."); MYL-AFL-BLA1079688 at -1079702–1079704, at Section 14.1; MYL-AFL-BLA1079688 at -1079708–1079710, at Section 14.4; MYL-AFL0004715; MYL-AFL0006405; MYL-AFL0004715; Brown 2021.
5. The method of claim 3 wherein only two secondary doses are administered to the patient.	**Administration of aflibercept in accordance with Mylan's proposed labeling practices claim 3 as set forth above.** **Mylan's proposed labeling directs physicians to treat angiogenic eye disorders by administering to the patient only two secondary doses.** *See, e.g.*, MYL-AFL-BLA1079688, at Highlights of Prescribing Information ("The recommended dose for YESAFILI is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 3 months . . . ."); MYL-AFL-BLA1079688 at -1079689, at section 2.2 ("The recommended dose for YESAFILI is 2 mg (0.05 mL or 50 microliters) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 12 weeks (3 months) . . . ."); MYL-AFL-BLA1079688 at -1079702–1079704, at Section 14.1. **In accordance with Mylan's proposed labeling, physicians will treat angiogenic eye disorders by administering to the patient only two secondary doses.**

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	See, e.g., MYL-AFL-BLA1079688 at Highlights of Prescribing Information ("The recommended dose for YESAFILI is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 3 months . . . ."); MYL-AFL-BLA1079688 at -1079689, at section 2.2 ("The recommended dose for YESAFILI is 2 mg (0.05 mL or 50 microliters) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 12 weeks (3 months) . . . ."); MYL-AFL-BLA1079688 at -1079702–1079704, at Section 14.1.
6. The method of claim 3 wherein the aflibercept is formulated as an isotonic solution.	**Administration of aflibercept in accordance with Mylan's proposed labeling practices claim 3 as set forth above.** **Mylan's M710 is a product biosimilar to and/or interchangeable with aflibercept that is formulated as an isotonic solution.** *See, e.g.*, MYL-AFL-BLA0002879 at -0002881 (BLA section 3.2.P.2.2.1) ("M710 drug product (DP) has been developed as a biosimilar medicinal product of US-licensed reference product (RP) Eylea® (aflibercept), Regeneron Pharmaceuticals (RP), BLA 125387. Formulation development studies were directed towards identification of a formulation that is comparable to RP."), *id.* at -0002887 (BLA section 3.2.P.2.2.1.2.1.2)("The osmolality of all six formulations is close to isotonic (Table 3.2.P.2.2-11)."); *id.* at -0002903 (tbl. 3.2.P.2.2-11).
7. The method of claim 3 wherein the aflibercept is formulated with a nonionic surfactant.	**Administration of aflibercept in accordance with Mylan's proposed labeling practices claim 3 as set forth above.** **Mylan's M710 is a product biosimilar to and/or interchangeable with aflibercept that is formulated with a nonionic surfactant.** *See, e.g.*, MYL-AFL-BLA0002860 at -0002867 ("M710 is an aseptically filled drug product for intravitreal injection. It is a liquid being developed as a biosimilar to YESAFILI® (aflibercept) injection; MYL-AFL-BLA0002860 at -0002868 ("Histidine buffer is a pH adjuster and Polysorbate 20 a nonionic surfactant."); MYL-AFL-BLA0013850, at -13877; MYL-AFL-BLA1080797 at -1080833 (section 3.2.S.2.2.4.2.7) [redacted] Trehalose dihydrate, [redacted] PS20, pH 6.2

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	and [redacted] His–HCl, pH 6.2 is added to a final concentration of [redacted] Trehalose dihydrate, [redacted] PS20 and [redacted] protein concentration.").
8. The method of claim 2 wherein the patient gains at least 8 letters Best Corrected Visual Acuity (BCVA) according to Early Treatment Diabetic Retinopathy Study (ETDRS) letter score.	**Administration of aflibercept in accordance with Mylan's proposed labeling practices claim 2 as set forth above.** **Mylan's proposed labeling directs physicians to administer aflibercept to treat angiogenic eye disorders such that a patient will gain at least 8 letters Best Corrected Visual Acuity (BCVA) according to Early Treatment Diabetic Retinopathy Study (ETDRS) letter score.** *See, e.g.*, MYL-AFL-BLA1079688 at -1079702–1079704, at section 14.1 ("The safety and efficacy of aflibercept were assessed in two randomized, multi-center, double-masked, active-controlled studies in patients with wet AMD. A total of 2412 patients were treated and evaluable for efficacy (1817 with aflibercept) in the two studies (VIEW1 and VIEW2). In each study, up to week 52, patients were randomly assigned in a 1:1:1:1 ratio to 1 of 4 dosing regimens: 1) aflibercept administered 2 mg every 8 weeks following 3 initial monthly doses (aflibercept 2Q8); 2) aflibercept administered 2 mg every 4 weeks (aflibercept 2Q4); 3) aflibercept 0.5 mg administered every 4 weeks (aflibercept 0.5Q4); and 4) ranibizumab administered 0.5 mg every 4 weeks (ranibizumab 0.5 mg Q4)."); MYL-AFL-BLA1079688 at -1079702–1079703, at section 14.1, tbl. 4 (showing that 31% (VIEW1 and VIEW2) of wet AMD patients treated with three monthly 2 mg doses of aflibercept followed by 2 mg doses administered once every 8 weeks gained at least 15 letters of vision (i.e., BCVA score)); MYL-AFL-BLA1079688 at -1079708–1079710, at Section 14.4; MYL-AFL-BLA1079688 at -1079710–1079713, at Section 14.5; MYL-AFL0006405; MYL-AFL0004715; Brown 2021. **In accordance with Mylan's proposed labeling, physicians will treat angiogenic eye disorders by using the method of claim 2, resulting in a patient gaining at least 8 letters Best Corrected Visual Acuity (BCVA) according to Early Treatment Diabetic Retinopathy Study (ETDRS) letter score.**

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	See, e.g., MYL-AFL-BLA1079688 at -1079702–1079704, at section 14.1 ("The safety and efficacy of aflibercept were assessed in two randomized, multi-center, double-masked, active-controlled studies in patients with wet AMD. A total of 2412 patients were treated and evaluable for efficacy (1817 with aflibercept) in the two studies (VIEW1 and VIEW2). In each study, up to week 52, patients were randomly assigned in a 1:1:1:1 ratio to 1 of 4 dosing regimens: 1) aflibercept administered 2 mg every 8 weeks following 3 initial monthly doses (aflibercept 2Q8); 2) aflibercept administered 2 mg every 4 weeks (aflibercept 2Q4); 3) aflibercept 0.5 mg administered every 4 weeks (aflibercept 0.5Q4); and 4) ranibizumab administered 0.5 mg every 4 weeks (ranibizumab 0.5 mg Q4)."); MYL-AFL-BLA1079688 at -1079702–1079703, at section 14.1, tbl. 4 (showing that 31% (VIEW1 and VIEW2) of wet AMD patients treated with three monthly 2 mg doses of aflibercept followed by 2 mg doses administered once every 8 weeks gained at least 15 letters of vision (i.e., BCVA score)); MYL-AFL-BLA1079688 at -1079708–1079710, at Section 14.4; MYL-AFL-BLA1079688 at -1079710–1079713, at Section 14.5; MYL-AFL0006405; MYL-AFL0004715; Brown 2021.
9. The method of claim 8 wherein the patient achieves the gain in visual acuity within 24 weeks following the initial dose.	**Administration of aflibercept in accordance with Mylan's proposed labeling practices claim 8 as set forth above.** **Mylan's proposed labeling directs physicians to administer aflibercept to treat angiogenic eye disorders such that a patient will achieve the gain in visual acuity within 24 weeks after the initial dose.** *See, e.g.*, MYL-AFL-BLA1079688 at -1079704–1079706, at section 14.2 ("In both studies, the primary efficacy endpoint was the proportion of patients who gained at least 15 letters in BCVA compared to baseline. At week 24, the aflibercept 2 mg Q4 group was superior to the control group for the primary endpoint."); MYL-AFL-BLA1079688 at -1079706–1079707, at section 14.3 ("In the VIBRANT study, the primary efficacy endpoint was the proportion of patients who gained at least 15 letters in BCVA at week 24 compared to baseline."); MYL-AFL-BLA1079688 at -1079710–1079713, at section 14.5 ("The primary efficacy endpoint was the proportion of patients who improved by ≥2 steps on the DRSS from baseline to week 24 in

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	the combined aflibercept groups and at week 52 in the 2Q16 and 2Q8 groups individually versus sham."); MYL-AFL-BLA1079688 at -1079702–1079704, at Section 14.1; MYL-AFL-BLA1079688 at -1079708–1079710, at Section 14.4; MYL-AFL0006405; MYL-AFL0004715; Brown 2021. **In accordance with Mylan's proposed labeling, physicians will treat angiogenic eye disorders by administering aflibercept such that a patient will achieve the gain in visual acuity within 24 weeks after the initial dose.** *See, e.g.*, MYL-AFL-BLA1079688 at -1079704–1079706 at section 14.2 ("In both studies, the primary efficacy endpoint was the proportion of patients who gained at least 15 letters in BCVA compared to baseline. At week 24, the aflibercept 2 mg Q4 group was superior to the control group for the primary endpoint."); MYL-AFL-BLA1079688 at -1079706–1079707, at section 14.3 ("In the VIBRANT study, the primary efficacy endpoint was the proportion of patients who gained at least 15 letters in BCVA at week 24 compared to baseline."); MYL-AFL-BLA1079688 at -1079710–1079713, at section 14.5 ("The primary efficacy endpoint was the proportion of patients who improved by ≥2 steps on the DRSS from baseline to week 24 in the combined aflibercept groups and at week 52 in the 2Q16 and 2Q8 groups individually versus sham."); MYL-AFL-BLA1079688 at -1079702–1079704, at Section 14.1; MYL-AFL0006405; MYL-AFL-BLA1079688 at -1079708–1079710, at Section 14.4; MYL-AFL0006405; MYL-AFL0004715; Brown 2021.
10. The method of claim 2 wherein the patient gains at least 9 letters Best Corrected Visual Acuity (BCVA) according to Early Treatment Diabetic Retinopathy Study (ETDRS) letter score.	**Administration of aflibercept in accordance with Mylan's proposed labeling practices claim 2 as set forth above.** **Mylan's proposed labeling directs physicians to administer aflibercept to treat angiogenic eye disorders such that a patient will gain at least 9 letters Best Corrected Visual Acuity (BCVA) according to Early Treatment Diabetic Retinopathy Study (ETDRS) letter score.** *See, e.g.*, MYL-AFL-BLA1079688 at -1079702–1079704, at section 14.1 ("The safety and efficacy of aflibercept were assessed in two randomized, multi-center, double-masked, active-controlled studies in patients with wet AMD. A total of

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	2412 patients were treated and evaluable for efficacy (1817 with aflibercept) in the two studies (VIEW1 and VIEW2). In each study, up to week 52, patients were randomly assigned in a 1:1:1:1 ratio to 1 of 4 dosing regimens: 1) aflibercept administered 2 mg every 8 weeks following 3 initial monthly doses (aflibercept 2Q8); 2) aflibercept administered 2 mg every 4 weeks (aflibercept 2Q4); 3) aflibercept 0.5 mg administered every 4 weeks (aflibercept 0.5Q4); and 4) ranibizumab administered 0.5 mg every 4 weeks (ranibizumab 0.5 mg Q4)."); MYL-AFL-BLA1079688 at -1079702–1079703, at section 14.1, tbl. 4 (showing that 31% (VIEW1 and VIEW2) of wet AMD patients treated with three monthly 2 mg doses of aflibercept followed by 2 mg doses administered once every 8 weeks gained at least 15 letters of vision (i.e., BCVA score)); MYL-AFL-BLA1079688 at -1079708–1079710, at Section 14.4; MYL-AFL-BLA1079688 at -1079710–1079713, at Section 14.5; MYL-AFL0006405; MYL-AFL0004715; Brown 2021. **In accordance with Mylan's proposed labeling, physicians will treat angiogenic eye disorders by using the method of claim 2, resulting in a patient gaining at least 9 letters Best Corrected Visual Acuity (BCVA) according to Early Treatment Diabetic Retinopathy Study (ETDRS) letter score.** *See, e.g.*, MYL-AFL-BLA1079688 at -1079702–1079704, at section 14.1 ("The safety and efficacy of aflibercept were assessed in two randomized, multi-center, double-masked, active-controlled studies in patients with wet AMD. A total of 2412 patients were treated and evaluable for efficacy (1817 with aflibercept) in the two studies (VIEW1 and VIEW2). In each study, up to week 52, patients were randomly assigned in a 1:1:1:1 ratio to 1 of 4 dosing regimens: 1) aflibercept administered 2 mg every 8 weeks following 3 initial monthly doses (aflibercept 2Q8); 2) aflibercept administered 2 mg every 4 weeks (aflibercept 2Q4); 3) aflibercept 0.5 mg administered every 4 weeks (aflibercept 0.5Q4); and 4) ranibizumab administered 0.5 mg every 4 weeks (ranibizumab 0.5 mg Q4)."); MYL-AFL-BLA1079688 at -1079702–1079703, at section 14.1, tbl. 4 (showing that 31% (VIEW1 and VIEW2) of wet AMD patients treated with three monthly 2 mg doses of aflibercept followed by 2 mg doses administered once every 8

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	weeks gained at least 15 letters of vision (i.e., BCVA score)); MYL-AFL-BLA1079688 at -1079708–1079710, at Section 14.4; MYL-AFL0004715; MYL-AFL-BLA1079688 at -1079710–1079713, at Section 14.5; MYL-AFL0006405; MYL-AFL0004715; Brown 2021.
11. The method of claim 10 wherein only two secondary doses are administered to the patient.	**Administration of aflibercept in accordance with Mylan's proposed labeling practices claim 10 as set forth above.** **Mylan's proposed labeling directs physicians to treat angiogenic eye disorders by administering to the patient only two secondary doses.** *See, e.g.*, MYL-AFL-BLA1079688 at Highlights of Prescribing Information ("The recommended dose for YESAFILI is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 3 months . . . ."); MYL-AFL-BLA1079688 at -107689, at section 2.2 ("The recommended dose for YESAFILI is 2 mg (0.05 mL or 50 microliters) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 12 weeks (3 months) . . . ."). **In accordance with Mylan's proposed labeling, physicians will treat angiogenic eye disorders by administering to the patient only two secondary doses.** *See, e.g.*, MYL-AFL-BLA1079688 at Highlights of Prescribing Information ("The recommended dose for YESAFILI is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 3 months . . . ."); MYL-AFL-BLA1079688 at -107689, at section 2.2 ("The recommended dose for YESAFILI is 2 mg (0.05 mL or 50 microliters) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 12 weeks (3 months) . . . .")
12. The method of claim 10 wherein the aflibercept is formulated as an isotonic solution.	**Administration of aflibercept in accordance with Mylan's proposed labeling practices claim 10 as set forth above.** **Mylan's M710 is a product biosimilar to and/or interchangeable with aflibercept that is formulated as an isotonic solution.**

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	See, e.g., MYL-AFL-BLA0002879 at -0002881 (BLA section 3.2.P.2.2.1) ("M710 drug product (DP) has been developed as a biosimilar medicinal product of US-licensed reference product (RP) Eylea® (aflibercept), Regeneron Pharmaceuticals (RP), BLA 125387. Formulation development studies were directed towards identification of a formulation that is comparable to RP."); *id.* at -0002887 (BLA section 3.2.P.2.2.1.2.1.2) ("The osmolality of all six formulations is close to isotonic (Table 3.2.P.2.2-11)."); *id.* at -0002903 (tbl. 3.2.P.2.2-11).
13. The method of claim 10 wherein the aflibercept is formulated with a nonionic surfactant.	**Administration of aflibercept in accordance with Mylan's proposed labeling practices claim 10 as set forth above.** **Mylan's M710 is a product biosimilar to and/or interchangeable with aflibercept that is formulated with a nonionic surfactant.** *See, e.g.*, MYL-AFL-BLA0002860 at -0002867 ("M710 is an aseptically filled drug product for intravitreal injection. It is a liquid being developed as a biosimilar to YESAFILI® (aflibercept) injection; MYL-AFL-BLA0002860 at -0002868 ("Histidine buffer is a pH adjuster and Polysorbate 20 a nonionic surfactant."); MYL-AFL-BLA0013850, at -13877; MYL-AFL-BLA10807972860 at -108833 (section 3.2.S.2.2.4.2.7) [redacted] Trehalose dihydrate, [redacted] PS20, pH 6.2 and [redacted] His–HCl, pH 6.2 is added to a final concentration of [redacted] Trehalose dihydrate, [redacted] PS20 and [redacted] protein concentration.").
14. The method of claim 1 wherein exclusion criteria for the patient include both of: (1) active ocular inflammation; and (2) active ocular or periocular infection.	**Administration of aflibercept in accordance with Mylan's proposed labeling practices claim 1 as set forth above.** **Mylan's proposed labeling directs physicians to treat angiogenic eye disorders using the method of claim 1, excluding patients that have active intraocular inflammation or active ocular or periocular infection.** *See, e.g.*, MYL-AFL-BLA1079688 at Highlights of Prescribing Information (listing as contraindications "Ocular or periocular infection" and "Active intraocular inflammation"); MYL-AFL-BLA1079688 at -1079694–1079695, at section 4.1 ("YESAFILI is contraindicated in patients with ocular or periocular infections."); MYL-AFL-BLA1079688 at -1079694–

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	1079695, at section 4.2 ("YESAFILI is contraindicated in patients with active intraocular inflammation."). **In accordance with Mylan's proposed labeling, physicians will treat angiogenic eye disorders by using the method of claim 1, excluding patients that have active intraocular inflammation or active ocular or periocular infection.** *See, e.g.*, MYL-AFL-BLA1079688 at Highlights of Prescribing Information (listing as contraindications "Ocular or periocular infection" and "Active intraocular inflammation"); MYL-AFL-BLA1079688 at -1079694–1079695, at section 4.1 ("YESAFILI is contraindicated in patients with ocular or periocular infections."); MYL-AFL-BLA1079688 at -1079694–1079695, at section 4.2 ("YESAFILI is contraindicated in patients with active intraocular inflammation.").
(15pre) 15. A method of treating diabetic macular edema in a patient in need thereof comprising	**Mylan's proposed labeling directs physicians to treat diabetic macular edema (DME) by administering aflibercept.** *See, e.g.*, MYL-AFL-BLA1079688 at Highlights of Prescribing Information ("YESAFILI™ (aflibercept-jbvf) is interchangeable* with EYLEA (aflibercept)."); MYL-AFL-BLA1079688, at -1079689 at section 1.3 ("YESAFILI is indicated for the treatment of . . . Diabetic Macular Edema (DME)".). **In accordance with Mylan's proposed labeling, physicians will administer aflibercept to treat diabetic macular edema.** *See, e.g.*, MYL-AFL-BLA1079688 at Highlights of Prescribing Information ("YESAFILI™ (aflibercept-jbvf) is interchangeable* with EYLEA (aflibercept)."); MYL-AFL-BLA1079688 at -1079689, at section 1.3 ("YESAFILI is indicated for the treatment of . . . Diabetic Macular Edema (DME)".).
(15a) sequentially administering to the patient a single initial dose of 2 mg of aflibercept, followed by one or more secondary doses of 2 mg of	**Mylan's proposed labeling directs physicians to treat diabetic macular edema by administering a single initial dose of 2 mg of aflibercept, followed by one or more secondary doses of 2 mg of aflibercept, followed by one or more tertiary doses of 2 mg of aflibercept.**

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aflibercept, followed by one or more tertiary doses of 2 mg of aflibercept;	*See, e.g.*, MYL-AFL-BLA1079688 at -1079689, at section 2.4 ("The recommended dose for YESAFILI is 2 mg (0.05 mL or 50 microliters) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 5 injections, followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months)."). **In accordance with Mylan's proposed labeling, physicians will treat diabetic macular edema by administering a single initial dose of 2 mg of aflibercept, followed by one or more secondary doses of 2 mg of aflibercept, followed by one or more tertiary doses of 2 mg of aflibercept.** *See, e.g.*, MYL-AFL-BLA1079688 at -1079689, at section 2.4 ("The recommended dose for YESAFILI is 2 mg (0.05 mL or 50 microliters) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 5 injections, followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months).").
(15b) wherein each secondary dose is administered to the patient by intravitreal injection approximately 4 weeks following the immediately preceding dose; and	**Mylan's proposed labeling directs physicians to treat diabetic macular edema by administering each secondary dose to the patient by intravitreal injection approximately 4 weeks following the immediately preceding dose.** *See, e.g.*, MYL-AFL-BLA1079688 at -1079689, at section 2.4 ("The recommended dose for YESAFILI is 2 mg (0.05 mL or 50 microliters) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 5 injections, followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months)."). **In accordance with Mylan's proposed labeling, physicians will treat diabetic macular edema by administering each secondary dose to the patient by intravitreal injection approximately 4 weeks following the immediately preceding dose.** *See, e.g.*, MYL-AFL-BLA1079688 at -1079689, at section 2.4 ("The recommended dose for YESAFILI is 2 mg (0.05 mL or 50 microliters) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 5 injections, followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months)..").

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(15c) wherein each tertiary dose is administered to the patient by intravitreal injection approximately 8 weeks following the immediately preceding dose.	**Mylan's proposed labeling directs physicians to treat diabetic macular edema by administering each tertiary dose to the patient by intravitreal injection approximately 8 weeks following the immediately preceding dose.** *See, e.g.*, MYL-AFL-BLA1079688 at -1079689, at section 2.4 ("The recommended dose for YESAFILI is 2 mg (0.05 mL or 50 microliters) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 5 injections, followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months)."). **In accordance with Mylan's proposed labeling, physicians will treat diabetic macular edema by administering each tertiary dose to the patient by intravitreal injection approximately 8 weeks following the immediately preceding dose.** *See, e.g.*, MYL-AFL-BLA1079688 at -1079689, at section 2.4 ("The recommended dose for YESAFILI is 2 mg (0.05 mL or 50 microliters) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 5 injections, followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months).").
16. The method of claim 15 wherein the patient achieves a gain in visual acuity within 52 weeks following the initial dose.	**Administration of aflibercept in accordance with Mylan's proposed labeling practices claim 15 as set forth above.** **Mylan's proposed labeling directs physicians to administer aflibercept to treat diabetic macular edema such that a patient will achieve a gain in visual acuity within 52 weeks after the initial dose.** *See, e.g.*, MYL-AFL-BLA1079688 at -1079702–1079704, at section 14.1 ("In both studies, the primary efficacy endpoint was the proportion of patients who maintained vision, defined as losing fewer than 15 letters of visual acuity at week 52 compared to baseline. Both aflibercept 2Q8 and aflibercept 2Q4 groups were shown to have efficacy that was clinically equivalent to the ranibizumab 0.5 mg Q4 group in year 1."); MYL-AFL-BLA1079688 at -1079704–1079706, at section 14.2 ("In both studies, the primary efficacy endpoint was the proportion of patients who gained at least 15 letters in BCVA

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	compared to baseline. At week 24, the aflibercept 2 mg Q4 group was superior to the control group for the primary endpoint."); MYL-AFL-BLA1079688 at -1079706–1079707, at section 14.3 ("In the VIBRANT study, the primary efficacy endpoint was the proportion of patients who gained at least 15 letters in BCVA at week 24 compared to baseline."); MYL-AFL-BLA1079688 at -1079708–1079710, at section 14.4 ("In both studies, the primary efficacy endpoint was the mean change from baseline in BCVA at week 52 as measured by ETDRS letter score."); MYL-AFL-BLA1079688 at -1079710–1079713, at section 14.5 ("The primary efficacy endpoint was the proportion of patients who improved by ≥2 steps on the DRSS from baseline to week 24 in the combined aflibercept groups and at week 52 in the 2Q16 and 2Q8 groups individually versus sham."); MYL-AFL0004715; MYL-AFL-BLA1079688 at -1079708–1079710, at Section 14.4 (Table 7 & Fig. 16)). **In accordance with Mylan's proposed labeling, physicians will treat diabetic macular edema by administering aflibercept such that a patient will achieve a gain in visual acuity within 52 weeks after the initial dose.** *See, e.g.*, MYL-AFL-BLA1079688 at -1079702–1079704, at section 14.1 ("In both studies, the primary efficacy endpoint was the proportion of patients who maintained vision, defined as losing fewer than 15 letters of visual acuity at week 52 compared to baseline. Both aflibercept 2Q8 and aflibercept 2Q4 groups were shown to have efficacy that was clinically equivalent to the ranibizumab 0.5 mg Q4 group in year 1."); MYL-AFL-BLA1079688 at -1079704–1079706, at section 14.2 ("In both studies, the primary efficacy endpoint was the proportion of patients who gained at least 15 letters in BCVA compared to baseline. At week 24, the aflibercept 2 mg Q4 group was superior to the control group for the primary endpoint."); MYL-AFL-BLA1079688 at -1079706–1079707, at section 14.3 ("In the VIBRANT study, the primary efficacy endpoint was the proportion of patients who gained at least 15 letters in BCVA at week 24 compared to baseline."); MYL-AFL-BLA1079688 at -1079708–1079710, at section 14.4 ("In both studies, the primary efficacy endpoint was the mean change from baseline in BCVA at week 52 as measured by ETDRS letter score."); MYL-AFL-BLA1079688 at -1079710–1079713, at section 14.5 ("The primary efficacy endpoint was

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	the proportion of patients who improved by ≥2 steps on the DRSS from baseline to week 24 in the combined aflibercept groups and at week 52 in the 2Q16 and 2Q8 groups individually versus sham."); MYL-AFL-BLA1079688 at -1079708–1079710, at Section 14.4 ("In both studies, the primary efficacy endpoint was the mean change from baseline in BCVA at week 52 as measured by ETDRS letter score. Efficacy of both aflibercept 2Q8 and aflibercept 2Q4 groups was statistically superior to the control group. This statistically superior improvement in BCV A was maintained at week 100 in both studies."); *id.* (Table 7 & Fig. 16); MYL-AFL0004715.
17. The method of claim 16 wherein the patient gains at least 9 letters Best Corrected Visual Acuity (BCVA) according to Early Treatment Diabetic Retinopathy Study (ETDRS) letter score.	**Administration of aflibercept in accordance with Mylan's proposed labeling practices claim 16 as set forth above.** **Mylan's proposed labeling directs physicians to administer aflibercept to treat diabetic macular edema such that a patient will gain at least 9 letters Best Corrected Visual Acuity (BCVA) according to Early Treatment Diabetic Retinopathy Study (ETDRS) letter score.** *See, e.g.*, MYL-AFL-BLA1079688 at Highlights of Prescribing Information ("YESAFILI™ (aflibercept-jbvf) is interchangeable* with EYLEA (aflibercept)."); MYL-AFL-BLA1079688 at -1079708–1079710, at section 14.4 ("The safety and efficacy of aflibercept were assessed in two randomized, multi-center, double-masked, controlled studies in patients with DME. A total of 862 randomized and treated patients were evaluable for efficacy. Protocol-specified visits occurred every 28±7 days. Patient ages ranged from 23 to 87 years with a mean of 63 years. Of those, 576 were randomized to aflibercept groups in the two studies (VIVID and VISTA). In each study, patients were randomly assigned in a 1:1:1 ratio to 1 of 3 dosing regimens: 1) aflibercept administered 2 mg every 8 weeks following 5 initial monthly injections (aflibercept 2Q8); 2) aflibercept administered 2 mg every 4 weeks (aflibercept 2Q4); and 3) macular laser photocoagulation (at baseline and then as needed). Beginning at week 24, patients meeting a pre-specified threshold of vision loss were eligible to receive additional treatment: patients in the aflibercept groups could receive laser and patients in the laser group could receive aflibercept. In both studies, the primary efficacy endpoint was the mean change from baseline in BCVA at week 52 as

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	measured by ETDRS letter score."); MYL-AFL-BLA1079688 at -1079708–1079709, at section 14.4, tbl. 7 (showing that 33.3% of 2Q8 DME patients (VIVID) and 33.1% of 2Q8 DME patients (VISTA) gained at least 15 letters in BCVA from baseline); MYL-AFL0004715. **In accordance with Mylan's proposed labeling, physicians will treat diabetic macular edema by using the method of claim 16, resulting in a patient gaining at least 9 letters Best Corrected Visual Acuity (BCVA) according to Early Treatment Diabetic Retinopathy Study (ETDRS) letter score.** *See, e.g.*, MYL-AFL- at Highlights of Prescribing Information ("YESAFILI™ (aflibercept-jbvf) is interchangeable* with EYLEA (aflibercept)."); MYL-AFL-BLA1079688 at -1079708–1079710, at section 14.4 ("The safety and efficacy of aflibercept were assessed in two randomized, multi-center, double-masked, controlled studies in patients with DME. A total of 862 randomized and treated patients were evaluable for efficacy. Protocol-specified visits occurred every 28±7 days. Patient ages ranged from 23 to 87 years with a mean of 63 years. Of those, 576 were randomized to aflibercept groups in the two studies (VIVID and VISTA). In each study, patients were randomly assigned in a 1:1:1 ratio to 1 of 3 dosing regimens: 1) aflibercept administered 2 mg every 8 weeks following 5 initial monthly injections (aflibercept 2Q8); 2) aflibercept administered 2 mg every 4 weeks (aflibercept 2Q4); and 3) macular laser photocoagulation (at baseline and then as needed). Beginning at week 24, patients meeting a pre-specified threshold of vision loss were eligible to receive additional treatment: patients in the aflibercept groups could receive laser and patients in the laser group could receive aflibercept. In both studies, the primary efficacy endpoint was the mean change from baseline in BCVA at week 52 as measured by ETDRS letter score."); MYL-AFL-BLA1079688 at -1079708–1079709, at section 14.4, tbl. 7 (showing that 33.3% of 2Q8 DME patients (VIVID) and 33.1% of 2Q8 DME patients (VISTA) gained at least 15 letters in BCVA from baseline); MYL-AFL0004715.
18. The method of claim 17 wherein the aflibercept is	**Administration of aflibercept in accordance with Mylan's proposed labeling practices claim 17 as set forth above.**

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formulated as an isotonic solution.	**Mylan's M710 is a product biosimilar to and/or interchangeable with aflibercept that is formulated as an isotonic solution.** *See, e.g.*, MYL-AFL-BLA0002879 at -0002881 (BLA section 3.2.P.2.2.1) ("M710 drug product (DP) has been developed as a biosimilar medicinal product of US-licensed reference product (RP) Eylea® (aflibercept), Regeneron Pharmaceuticals (RP), BLA 125387. Formulation development studies were directed towards identification of a formulation that is comparable to RP."); *id.* at -0002887 (BLA section 3.2.P.2.2.1.2.1.2) ("The osmolality of all six formulations is close to isotonic (Table 3.2.P.2.2-11)."); *id.* at -0002903 (tbl. 3.2.P.2.2-11).
19. The method of claim 17 wherein the aflibercept is formulated with a non-ionic surfactant.	**Administration of aflibercept in accordance with Mylan's proposed labeling practices claim 17 as set forth above.** **Mylan's M710 is a product biosimilar to and/or interchangeable with aflibercept that is formulated with a nonionic surfactant.** *See, e.g.*, MYL-AFL-BLA0002860 at -0002867 ("M710 is an aseptically filled drug product for intravitreal injection. It is a liquid being developed as a biosimilar to YESAFILI® (aflibercept) injection; MYL-AFL-BLA0002860 at -0002868 ("Histidine buffer is a pH adjuster and Polysorbate 20 a nonionic surfactant."); MYL-AFL-BLA0013850, at -13877; MYL-AFL-BLA108079 at -1080833 (section 3.2.S.2.2.4.2.7) [redacted] Trehalose dihydrate, [redacted] PS20, pH 6.2 and [redacted] His–HCl, pH 6.2 is added to a final concentration of [redacted] Trehalose dihydrate, [redacted] PS20 and [redacted] protein concentration.").
20. The method of claim 17 wherein the patient achieves a gain in visual acuity within 24 weeks following the initial dose.	**Administration of aflibercept in accordance with Mylan's proposed labeling practices claim 17 as set forth above.** **Mylan's proposed labeling directs physicians to administer aflibercept to treat diabetic macular edema such that a patient will achieve the gain in visual acuity within 24 weeks after the initial dose.** *See, e.g.*, MYL-AFL-BLA1079688 at -1079708–1079710, at section 14.4, tbl. 7, fig. 16 (showing a gain in visual acuity

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	within 24 weeks); MYL-AFL-BLA1079688 at -1079710–1079713, at section 14.5 ("In the VIVID and VISTA studies, an efficacy outcome was the change in the Early Treatment Diabetic Retinopathy Study (ETDRS) Diabetic Retinopathy Severity Scale (ETDRS-DRSS). The ETDRS-DRSS score was assessed at baseline and approximately every 6 months thereafter for the duration of the studies [*see Clinical Studies* (14.4)]."); MYL-AFL-BLA1079688 at -1079710–1079713, at section 14.5 ("The primary efficacy endpoint was the proportion of patients who improved by ≥2 steps on the DRSS from baseline to week 24 in the combined aflibercept groups and at week 52 in the 2Q16 and 2Q8 groups individually versus sham."); MYL-AFL0004715. **In accordance with Mylan's proposed labeling, physicians will treat angiogenic eye disorders by administering aflibercept such that a patient will achieve the gain in visual acuity within 24 weeks after the initial dose.** *See, e.g.*, MYL-AFL-BLA1079688 at -1079708–1079710at section 14.4, tbl. 7, fig. 16 (showing a gain in visual acuity within 24 weeks); MYL-AFL-BLA1079688 at -1079710–1079713, at section 14.5 ("In the VIVID and VISTA studies, an efficacy outcome was the change in the Early Treatment Diabetic Retinopathy Study (ETDRS) Diabetic Retinopathy Severity Scale (ETDRS-DRSS). The ETDRS-DRSS score was assessed at baseline and approximately every 6 months thereafter for the duration of the studies [*see Clinical Studies* (14.4)]."); MYL-AFL-BLA1079688 at -1079710–1079713, at section 14.5 ("The primary efficacy endpoint was the proportion of patients who improved by ≥2 steps on the DRSS from baseline to week 24 in the combined aflibercept groups and at week 52 in the 2Q16 and 2Q8 groups individually versus sham."); MYL-AFL0004715.
21. The method of claim 16 wherein the patient gains at least 8 letters Best Corrected Visual Acuity (BCVA) according to Early Treatment Diabetic Retinopathy Study (ETDRS) letter score.	**Administration of aflibercept in accordance with Mylan's proposed labeling practices claim 16 as set forth above.** **Mylan's proposed labeling directs physicians to administer aflibercept to treat diabetic macular edema such that a patient will gain at least 8 letters Best Corrected Visual Acuity (BCVA) according to Early Treatment Diabetic Retinopathy Study (ETDRS) letter score.**

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	See, e.g., MYL-AFL-BLA1079688 at Highlights of Prescribing Information ("YESAFILI™ (aflibercept-jbvf) is interchangeable* with EYLEA (aflibercept)."); MYL-AFL-BLA1079688 at -1079708–1079710, at section 14.4 ("The safety and efficacy of aflibercept were assessed in two randomized, multi-center, double-masked, controlled studies in patients with DME. A total of 862 randomized and treated patients were evaluable for efficacy. Protocol-specified visits occurred every 28±7 days. Patient ages ranged from 23 to 87 years with a mean of 63 years. Of those, 576 were randomized to aflibercept groups in the two studies (VIVID and VISTA). In each study, patients were randomly assigned in a 1:1:1 ratio to 1 of 3 dosing regimens: 1) aflibercept administered 2 mg every 8 weeks following 5 initial monthly injections (aflibercept 2Q8); 2) aflibercept administered 2 mg every 4 weeks (aflibercept 2Q4); and 3) macular laser photocoagulation (at baseline and then as needed). Beginning at week 24, patients meeting a pre-specified threshold of vision loss were eligible to receive additional treatment: patients in the aflibercept groups could receive laser and patients in the laser group could receive aflibercept. In both studies, the primary efficacy endpoint was the mean change from baseline in BCVA at week 52 as measured by ETDRS letter score."); MYL-AFL-BLA1079688 at -1079708–1079709, at section 14.4, tbl. 7 (showing that 33.3% of 2Q8 DME patients (VIVID) and 33.1% of 2Q8 DME patients (VISTA) gained at least 15 letters in BCVA from baseline); MYL-AFL-BLA1079688 at -1079709–1079710, at section 14.4, fig. 16; MYL-AFL0004715. **In accordance with Mylan's proposed labeling, physicians will treat diabetic macular edema by using the method of claim 16, resulting in a patient gaining at least 8 letters Best Corrected Visual Acuity (BCVA) according to Early Treatment Diabetic Retinopathy Study (ETDRS) letter score.** *See, e.g.*, MYL-AFL-BLA1079688 at Highlights of Prescribing Information ("YESAFILI™ (aflibercept-jbvf) is interchangeable* with EYLEA (aflibercept)."); MYL-AFL-BLA1079688 at -1079708–1079710, at section 14.4 ("The safety and efficacy of aflibercept were assessed in two randomized, multi-center, double-masked, controlled studies in

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	patients with DME. A total of 862 randomized and treated patients were evaluable for efficacy. Protocol-specified visits occurred every 28±7 days. Patient ages ranged from 23 to 87 years with a mean of 63 years. Of those, 576 were randomized to aflibercept groups in the two studies (VIVID and VISTA). In each study, patients were randomly assigned in a 1:1:1 ratio to 1 of 3 dosing regimens: 1) aflibercept administered 2 mg every 8 weeks following 5 initial monthly injections (aflibercept 2Q8); 2) aflibercept administered 2 mg every 4 weeks (aflibercept 2Q4); and 3) macular laser photocoagulation (at baseline and then as needed). Beginning at week 24, patients meeting a pre-specified threshold of vision loss were eligible to receive additional treatment: patients in the aflibercept groups could receive laser and patients in the laser group could receive aflibercept. In both studies, the primary efficacy endpoint was the mean change from baseline in BCVA at week 52 as measured by ETDRS letter score.”); MYL-AFL-BLA1079688 at -1079708–1079709, at section 14.4, tbl. 7 (showing that 33.3% of 2Q8 DME patients (VIVID) and 33.1% of 2Q8 DME patients (VISTA) gained at least 15 letters in BCVA from baseline); MYL-AFL-BLA1079688 at -1079709–1079710, at section 14.4 (fig. 16); MYL-AFL0004715.
22. The method of claim 21 wherein the aflibercept is formulated as an isotonic solution.	**Administration of aflibercept in accordance with Mylan’s proposed labeling practices claim 21 as set forth above.** **Mylan’s M710 is a product biosimilar to and/or interchangeable with aflibercept that is formulated as an isotonic solution.** *See, e.g.*, MYL-AFL-BLA0002879 at -0002881 (BLA section 3.2.P.2.2.1) (“M710 drug product (DP) has been developed as a biosimilar medicinal product of US-licensed reference product (RP) Eylea® (aflibercept), Regeneron Pharmaceuticals (RP), BLA 125387. Formulation development studies were directed towards identification of a formulation that is comparable to RP.”); *id.* at -0002887 (BLA section 3.2.P.2.2.1.2.1.2) (“The osmolality of all six formulations is close to isotonic (Table 3.2.P.2.2-11).”); *id.* at -0002903 (tbl. 3.2.P.2.2-11).
23. The method of claim 21 wherein the aflibercept is	**Administration of aflibercept in accordance with Mylan’s proposed labeling practices claim 21 as set forth above.**

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formulated with a nonionic surfactant.	**Mylan's M710 is a is a product biosimilar to and/or interchangeable with aflibercept that is formulated with a nonionic surfactant.** *See, e.g.*, MYL-AFL-BLA0002860 at -0002867 ("M710 is an aseptically filled drug product for intravitreal injection. It is a liquid being developed as a biosimilar to YESAFILI® (aflibercept) injection; MYL-AFL-BLA0002860 at -0002868 ("Histidine buffer is a pH adjuster and Polysorbate 20 a nonionic surfactant."); MYL-AFL-BLA0013850, at -13877; MYL-AFL-BLA108079 at -1080833 (section 3.2.S.2.2.4.2.7) [redacted] Trehalose dihydrate, [redacted] PS20, pH 6.2 and [redacted] His–HCl, pH 6.2 is added to a final concentration of [redacted] Trehalose dihydrate, [redacted] PS20 and [redacted] protein concentration.").
25. The method of claim 15 wherein four secondary doses are administered to the patient.	**Administration of aflibercept in accordance with Mylan's proposed labeling practices claim 15 as set forth above.** **Mylan's proposed labeling directs physicians to treat DME by administering four secondary doses of aflibercept.** *See, e.g.*, MYL-AFL-BLA1079688 at Highlights of Prescribing Information (directing that, for the treatment of DME and DR, "[t]he recommended dose for YESAFILI is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 5 injections followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months)"); MYL-AFL-BLA1079688 at -1079689, at section 2.4 ("The recommended dose for YESAFILI is 2 mg (0.05 mL or 50 microliters) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 5 injections, followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months)."). **In accordance with Mylan's proposed labeling, physicians will treat DME by administering four secondary doses of aflibercept.** *See, e.g.*, MYL-AFL-BLA1079688 at Highlights of Prescribing Information (directing that, for the treatment of DME and DR, "[t]he recommended dose for YESAFILI is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 5 injections

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	followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months)"); MYL-AFL-BLA1079688 at -1079689, at section 2.4 ("The recommended dose for YESAFILI is 2 mg (0.05 mL or 50 microliters) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 5 injections, followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months).").
(26pre) 26. A method of treating age related macular degeneration in a patient in need thereof comprising	**Mylan's proposed labeling directs physicians to treat age related macular degeneration (AMD) by administering aflibercept.** *See, e.g.*, MYL-AFL-BLA1079688 at Highlights of Prescribing Information ("YESAFILI™ (aflibercept-jbvf) is interchangeable* with EYLEA (aflibercept)."); MYL-AFL-BLA1079688 at -1079689, at section 1.1 ("YESAFILI is indicated for the treatment of . . . Neovascular (Wet) Age-Related Macular Degeneration (AMD)".). **In accordance with Mylan's proposed labeling, physicians will administer aflibercept to treat AMD.** *See, e.g.*, MYL-AFL-BLA1079688 at Highlights of Prescribing Information ("YESAFILI™ (aflibercept-jbvf) is interchangeable* with EYLEA (aflibercept)."); MYL-AFL-BLA1079688 at -1079689, at section 1.1 ("YESAFILI is indicated for the treatment of . . . Neovascular (Wet) Age-Related Macular Degeneration (AMD)".).
(26a) sequentially administering to the patient a single initial dose of 2 mg of aflibercept, followed by one or more secondary doses of 2 mg of aflibercept, followed by one or more tertiary doses of 2 mg of aflibercept;	**Mylan's proposed labeling directs physicians to treat wet AMD by administering a single initial dose of 2 mg of aflibercept, followed by one or more secondary doses of 2 mg of aflibercept, followed by one or more tertiary doses of 2 mg of aflibercept.** *See, e.g.*, MYL-AFL-BLA1079688 at Highlights of Prescribing Information (directing that, for the treatment of wet AMD, "[t]he recommended dose for YESAFILI is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 3 months, followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months)").

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	In accordance with Mylan's proposed labeling, physicians will treat wet AMD by administering a single initial dose of 2 mg of aflibercept, followed by one or more secondary doses of 2 mg of aflibercept, followed by one or more tertiary doses of 2 mg of aflibercept. *See, e.g.*, MYL-AFL-BLA1079688 at Highlights of Prescribing Information (directing that, for the treatment of wet AMD, "[t]he recommended dose for YESAFILI is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 3 months, followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months)").
(26b) wherein each secondary dose is administered to the patient by intravitreal injection approximately 4 weeks following the immediately preceding dose; and	**Mylan's proposed labeling directs physicians to treat wet AMD by administering each secondary dose of 2 mg of aflibercept by intravitreal injection approximately 4 weeks after the immediately preceding dose.** *See, e.g.*, MYL-AFL-BLA1079688 at Highlights of Prescribing Information ("The recommended dose for YESAFILI is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 3 months . . . ."); MYL-AFL-BLA1079688 at -1079689, at section 2.2 ("The recommended dose for YESAFILI is 2 mg (0.05 mL or 50 microliters) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 12 weeks (3 months) . . . ."). **In accordance with Mylan's proposed labeling, physicians will treat wet AMD by administering each secondary dose of 2 mg of aflibercept by intravitreal injection approximately 4 weeks after the immediately preceding dose.** *See, e.g.*, MYL-AFL-BLA1079688 at Highlights of Prescribing Information ("The recommended dose for YESAFILI is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 3 months . . . ."); MYL-AFL-BLA1079688 at -1079689, at section 2.2 ("The recommended dose for YESAFILI is 2 mg (0.05 mL or 50 microliters) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 12 weeks (3 months) . . . .")

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(26c) wherein each tertiary dose is administered to the patient by intravitreal injection approximately 8 weeks following the immediately preceding dose;	**Mylan's proposed labeling directs physicians to treat wet AMD by administering each tertiary dose of 2 mg of aflibercept by intravitreal injection approximately 8 weeks after the immediately preceding dose.** *See, e.g.*, MYL-AFL-BLA1079688 at Highlights of Prescribing Information ("The recommended dose for YESAFILI is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 3 months, followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months)."); MYL-AFL-BLA1079688 at -1079689, at section 2.2 ("The recommended dose for YESAFILI is 2 mg (0.05 mL or 50 microliters) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 12 weeks (3 months), followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months)."). **In accordance with Mylan's proposed labeling, physicians will treat wet AMD by administering each tertiary dose of 2 mg of aflibercept by intravitreal injection approximately 8 weeks after the immediately preceding dose.** *See, e.g.*, MYL-AFL-BLA1079688 at Highlights of Prescribing Information ("The recommended dose for YESAFILI is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 3 months, followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months)."); MYL-AFL-BLA1079688 at -1079689, at section 2.2 ("The recommended dose for YESAFILI is 2 mg (0.05 mL or 50 microliters) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 12 weeks (3 months), followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months).")
(26d) wherein the method is as effective in achieving a gain in visual acuity as monthly administration of 0.5 mg of ranibizumab by intravitreal injection in human subjects with age-related macular	**Mylan's proposed labeling directs physicians to administer aflibercept to treat AMD according to a method that is as effective in achieving a gain in visual acuity as monthly administration of 0.5 mg of ranibizumab by intravitreal injection in human subjects with age-related macular degeneration at 52 weeks following the initial dose.**

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degeneration at 52 weeks following the initial dose.	*See, e.g.*, MYL-AFL-BLA1079688 at -1079702–1079704, at section 14.1 ("In both studies, the primary efficacy endpoint was the proportion of patients who maintained vision, defined as losing fewer than 15 letters of visual acuity at week 52 compared to baseline. Both aflibercept 2Q8 and aflibercept 2Q4 groups were shown to have efficacy that was clinically equivalent to the ranibizumab 0.5 mg Q4 group in year 1."); MYL-AFL-BLA1079688 at -1079702–1079703, at section 14.1, tbl. 4; MYL-AFL0006405. **In accordance with Mylan's proposed labeling, physicians will treat AMD according to a method that is as effective in achieving a gain in visual acuity as monthly administration of 0.5 mg of ranibizumab by intravitreal injection in human subjects with age-related macular degeneration at 52 weeks following the initial dose.** *See, e.g.*, MYL-AFL-BLA1079688 at -1079702–1079704, at section 14.1 ("In both studies, the primary efficacy endpoint was the proportion of patients who maintained vision, defined as losing fewer than 15 letters of visual acuity at week 52 compared to baseline. Both aflibercept 2Q8 and aflibercept 2Q4 groups were shown to have efficacy that was clinically equivalent to the ranibizumab 0.5 mg Q4 group in year 1."); MYL-AFL-BLA1079688 at -1079702–1079703, at section 14.1, tbl. 4; MYL-AFL0006405.
27. The method of claim 26 wherein only two secondary doses are administered to the patient.	**Administration of aflibercept in accordance with Mylan's proposed labeling practices claim 26 as set forth above.** **Mylan's proposed labeling directs physicians to treat AMD by administering to the patient only two secondary doses.** *See, e.g.*, MYL-AFL-BLA1079688 at Highlights of Prescribing Information ("The recommended dose for YESAFILI is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 3 months . . . ."); MYL-AFL-BLA1079688 at -1079689, at section 2.2 ("The recommended dose for YESAFILI is 2 mg (0.05 mL or 50 microliters) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 12 weeks (3 months) . . . ."); MYL-AFL-BLA1079688 at -1079702–1079704, at Section 14.1.

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	In accordance with Mylan's proposed labeling, physicians will treat AMD by administering to the patient only two secondary doses. *See, e.g.*, MYL-AFL-BLA1079688 at Highlights of Prescribing Information ("The recommended dose for YESAFILI is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 3 months . . . ."); MYL-AFL-BLA1079688 at -1079689, at section 2.2 ("The recommended dose for YESAFILI is 2 mg (0.05 mL or 50 microliters) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 12 weeks (3 months) . . . ."); MYL-AFL-BLA1079688 at -1079702–1079704, at Section 14.1.
28. The method of claim 26 wherein the gain in visual acuity is measured using the Early Treatment Diabetic Retinopathy Study (ETDRS) letter score.	**Administration of aflibercept in accordance with Mylan's proposed labeling practices claim 26 as set forth above.** **Mylan's proposed labeling directs physicians to administer aflibercept to treat wet AMD according to a method where the gain in visual acuity is measured using the Early Treatment Diabetic Retinopathy Study (ETDRS) letter score.** *See, e.g.*, MYL-AFL-BLA1079688 at -1079702–1079704, at section 14.1 ("The safety and efficacy of aflibercept were assessed in two randomized, multi-center, double-masked, active-controlled studies in patients with wet AMD. A total of 2412 patients were treated and evaluable for efficacy (1817 with aflibercept) in the two studies (VIEW1 and VIEW2). In each study, up to week 52, patients were randomly assigned in a 1:1:1:1 ratio to 1 of 4 dosing regimens: 1) aflibercept administered 2 mg every 8 weeks following 3 initial monthly doses (aflibercept 2Q8); 2) aflibercept administered 2 mg every 4 weeks (aflibercept 2Q4); 3) aflibercept 0.5 mg administered every 4 weeks (aflibercept 0.5Q4); and 4) ranibizumab administered 0.5 mg every 4 weeks (ranibizumab 0.5 mg Q4)."); MYL-AFL-BLA1079688 at -1079702–1079703, at section 14.1, tbl. 4 (showing that 31% (VIEW1 and VIEW2) of wet AMD patients treated with three monthly 2 mg doses of aflibercept followed by 2 mg doses administered once every 8 weeks gained at least 15 letters of vision (i.e., BCVA score)); MYL-AFL0006405.

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	In accordance with Mylan's proposed labeling, physicians will treat wet AMD according to a method where the gain in visual acuity is measured using the Early Treatment Diabetic Retinopathy Study (ETDRS) letter score. *See, e.g.*, MYL-AFL-BLA1079688 at -1079702–1079704, at section 14.1 ("The safety and efficacy of aflibercept were assessed in two randomized, multi-center, double-masked, active-controlled studies in patients with wet AMD. A total of 2412 patients were treated and evaluable for efficacy (1817 with aflibercept) in the two studies (VIEW1 and VIEW2). In each study, up to week 52, patients were randomly assigned in a 1:1:1:1 ratio to 1 of 4 dosing regimens: 1) aflibercept administered 2 mg every 8 weeks following 3 initial monthly doses (aflibercept 2Q8); 2) aflibercept administered 2 mg every 4 weeks (aflibercept 2Q4); 3) aflibercept 0.5 mg administered every 4 weeks (aflibercept 0.5Q4); and 4) ranibizumab administered 0.5 mg every 4 weeks (ranibizumab 0.5 mg Q4)."); MYL-AFL-BLA1079688 at -1079702–1079703, at section 14.1, tbl. 4 (showing that 31% (VIEW1 and VIEW2) of wet AMD patients treated with three monthly 2 mg doses of aflibercept followed by 2 mg doses administered once every 8 weeks gained at least 15 letters of vision (i.e., BCVA score)); MYL-AFL0006405.
(29pre) 29. A method of treating age-related macular degeneration in a patient in need thereof comprising	**Mylan's proposed labeling directs physicians to treat age related macular degeneration (AMD) by administering aflibercept.** *See, e.g.*, MYL-AFL-BLA1079688 at Highlights of Prescribing Information ("YESAFILI™ (aflibercept-jbvf) is interchangeable* with EYLEA (aflibercept)."); MYL-AFL-BLA1079688, at -1079689 at section 1.1 ("YESAFILI is indicated for the treatment of . . . Neovascular (Wet) Age-Related Macular Degeneration (AMD)".). **In accordance with Mylan's proposed labeling, physicians will administer aflibercept to treat AMD.** *See, e.g.*, MYL-AFL-BLA1079688 at Highlights of Prescribing Information ("YESAFILI™ (aflibercept-jbvf) is interchangeable* with EYLEA (aflibercept)."); MYL-AFL-BLA1079688, at -1079689, at section 1.1 ("YESAFILI is

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	indicated for the treatment of . . . Neovascular (Wet) Age-Related Macular Degeneration (AMD)".).
(29a) sequentially administering to the patient a single initial dose of 2 mg of aflibercept, followed by one or more secondary doses of 2 mg of aflibercept, followed by one or more tertiary doses of 2 mg of aflibercept;	**Mylan's proposed labeling directs physicians to treat wet AMD by administering a single initial dose of 2 mg of aflibercept, followed by one or more secondary doses of 2 mg of aflibercept, followed by one or more tertiary doses of 2 mg of aflibercept.** *See, e.g.*, MYL-AFL-BLA1079688 at Highlights of Prescribing Information (directing that, for the treatment of wet AMD, "[t]he recommended dose for YESAFILI is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 3 months, followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months)"); MYL-AFL-BLA1079688 at -1079689, at section 2.2 ("The recommended dose for YESAFILI is 2 mg (0.05 mL or 50 microliters) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 12 weeks (3 months) . . . ."). **In accordance with Mylan's proposed labeling, physicians will treat wet AMD by administering a single initial dose of 2 mg of aflibercept, followed by one or more secondary doses of 2 mg of aflibercept, followed by one or more tertiary doses of 2 mg of aflibercept.** *See, e.g.*, MYL-AFL-BLA1079688 at Highlights of Prescribing Information (directing that, for the treatment of wet AMD, "[t]he recommended dose for YESAFILI is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 3 months, followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months)"); MYL-AFL-BLA1079688 at -1079689, at section 2.2 ("The recommended dose for YESAFILI is 2 mg (0.05 mL or 50 microliters) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 12 weeks (3 months) . . . .")
(29b) wherein each secondary dose is administered to the patient by intravitreal injection	**Mylan's proposed labeling directs physicians to treat wet AMD by administering each secondary dose of 2 mg of aflibercept by intravitreal injection approximately 4 weeks after the immediately preceding dose.**

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approximately 4 weeks following the immediately preceding dose; and	*See, e.g.*, MYL-AFL-BLA1079688 at Highlights of Prescribing Information ("The recommended dose for YESAFILI is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 3 months . . . ."); MYL-AFL-BLA1079688 at -1079689, at section 2.2 ("The recommended dose for YESAFILI is 2 mg (0.05 mL or 50 microliters) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 12 weeks (3 months) . . . ."). **In accordance with Mylan's proposed labeling, physicians will treat wet AMD by administering each secondary dose of 2 mg of aflibercept by intravitreal injection approximately 4 weeks after the immediately preceding dose.** *See, e.g.*, MYL-AFL-BLA1079688 at Highlights of Prescribing Information ("The recommended dose for YESAFILI is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 3 months . . . ."); MYL-AFL-BLA1079688 at -1079689, at section 2.2 ("The recommended dose for YESAFILI is 2 mg (0.05 mL or 50 microliters) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 12 weeks (3 months) . . . .")
(29c) wherein each tertiary dose is administered to the patient by intravitreal injection approximately 8 weeks following the immediately preceding dose;	**Mylan's proposed labeling directs physicians to treat wet AMD by administering each tertiary dose of 2 mg of aflibercept by intravitreal injection approximately 8 weeks after the immediately preceding dose.** *See, e.g.*, MYL-AFL-BLA1079688 at Highlights of Prescribing Information ("The recommended dose for YESAFILI is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 3 months, followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months)."); MYL-AFL-BLA1079688 at -1079689 at section 2.2 ("The recommended dose for YESAFILI is 2 mg (0.05 mL or 50 microliters) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 12 weeks (3 months), followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months).").

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	In accordance with Mylan's proposed labeling, physicians will treat wet AMD by administering each tertiary dose of 2 mg of aflibercept by intravitreal injection approximately 8 weeks after the immediately preceding dose. *See, e.g.*, MYL-AFL-BLA1079688 at Highlights of Prescribing Information ("The recommended dose for YESAFILI is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 3 months, followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months)."); MYL-AFL-BLA1079688 at -1079689, at section 2.2 ("The recommended dose for YESAFILI is 2 mg (0.05 mL or 50 microliters) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 12 weeks (3 months), followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months).").
(29d) wherein the method is as effective in maintaining visual acuity as monthly administration of 0.5 mg of ranibizumab by intravitreal injection in human subjects with age-related macular degeneration at 52 weeks following the initial dose.	**Mylan's proposed labeling directs physicians to administer aflibercept to treat AMD according to a method that is as effective in maintaining visual acuity as monthly administration of 0.5 mg of ranibizumab by intravitreal injection in human subjects with age-related macular degeneration at 52 weeks following the initial dose.** *See, e.g.*, MYL-AFL-BLA1079688 at -1079702–1079704, at section 14.1 ("In both studies, the primary efficacy endpoint was the proportion of patients who maintained vision, defined as losing fewer than 15 letters of visual acuity at week 52 compared to baseline. Both aflibercept 2Q8 and aflibercept 2Q4 groups were shown to have efficacy that was clinically equivalent to the ranibizumab 0.5 mg Q4 group in year 1."); MYL-AFL0006405. **In accordance with Mylan's proposed labeling, physicians will treat AMD according to a method that is as effective in maintaining visual acuity as monthly administration of 0.5 mg of ranibizumab by intravitreal injection in human subjects with age-related macular degeneration at 52 weeks following the initial dose.** *See, e.g.*, MYL-AFL-BLA1079688 at -1079702–1079704, at section 14.1 ("In both studies, the primary efficacy endpoint was the proportion of patients who maintained vision, defined

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	as losing fewer than 15 letters of visual acuity at week 52 compared to baseline. Both aflibercept 2Q8 and aflibercept 2Q4 groups were shown to have efficacy that was clinically equivalent to the ranibizumab 0.5 mg Q4 group in year 1."); MYL-AFL0006405.
30. The method of claim 29 wherein maintenance of visual acuity means loss of less than 15 letters Best Corrected Visual Acuity (BCVA) as measured by using the Early Treatment Diabetic Retinopathy Study (ETDRS) letter score.	**Administration of aflibercept in accordance with Mylan's proposed labeling practices claim 29 as set forth above.** **Mylan's proposed labeling directs physicians to administer aflibercept to treat wet AMD according to a method where maintenance of visual acuity means loss of less than 15 letters Best Corrected Visual Acuity (BCVA) as measured by using the Early Treatment Diabetic Retinopathy Study (ETDRS) letter score.** *See, e.g.*, MYL-AFL-BLA1079688 at Highlights of Prescribing Information ("YESAFILI™ (aflibercept-jbvf) is interchangeable* with EYLEA (aflibercept)."); MYL-AFL-BLA1079688 at -1079702–1079704, at section 14.1 ("The safety and efficacy of aflibercept were assessed in two randomized, multi-center, double-masked, active-controlled studies in patients with wet AMD. A total of 2412 patients were treated and evaluable for efficacy (1817 with aflibercept) in the two studies (VIEW1 and VIEW2). In each study, up to week 52, patients were randomly assigned in a 1:1:1:1 ratio to 1 of 4 dosing regimens: 1) aflibercept administered 2 mg every 8 weeks following 3 initial monthly doses (aflibercept 2Q8); 2) aflibercept administered 2 mg every 4 weeks (aflibercept 2Q4); 3) aflibercept 0.5 mg administered every 4 weeks (aflibercept 0.5Q4); and 4) ranibizumab administered 0.5 mg every 4 weeks (ranibizumab 0.5 mg Q4). In both studies, the primary efficacy endpoint was the proportion of patients who maintained vision, defined as losing fewer than 15 letters of visual acuity at week 52 compared to baseline."); MYL-AFL-BLA1079688 at -1079702–1079703, at section 14.1, tbl. 4 (showing that 94% (VIEW1) and 95% (VIEW2) of wet AMD patients treated with three monthly 2 mg doses of aflibercept followed by 2 mg doses administered once every 8 weeks maintained visual acuity (%) (<15 letters of BCVA loss)); MYL-AFL0006405. **In accordance with Mylan's proposed labeling, physicians will treat wet AMD according to a method where**

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	maintenance of visual acuity means loss of less than 15 letters Best Corrected Visual Acuity (BCVA) as measured by using the Early Treatment Diabetic Retinopathy Study (ETDRS) letter score. *See, e.g.*, MYL-AFL-BLA1079688 at Highlights of Prescribing Information ("YESAFILI™ (aflibercept-jbvf) is interchangeable* with EYLEA (aflibercept)."); MYL-AFL-BLA1079688 at -1079702–1079704, at section 14.1 ("The safety and efficacy of aflibercept were assessed in two randomized, multi-center, double-masked, active-controlled studies in patients with wet AMD. A total of 2412 patients were treated and evaluable for efficacy (1817 with aflibercept) in the two studies (VIEW1 and VIEW2). In each study, up to week 52, patients were randomly assigned in a 1:1:1:1 ratio to 1 of 4 dosing regimens: 1) aflibercept administered 2 mg every 8 weeks following 3 initial monthly doses (aflibercept 2Q8); 2) aflibercept administered 2 mg every 4 weeks (aflibercept 2Q4); 3) aflibercept 0.5 mg administered every 4 weeks (aflibercept 0.5Q4); and 4) ranibizumab administered 0.5 mg every 4 weeks (ranibizumab 0.5 mg Q4). In both studies, the primary efficacy endpoint was the proportion of patients who maintained vision, defined as losing fewer than 15 letters of visual acuity at week 52 compared to baseline."); MYL-AFL-BLA1079688 at -1079702–1079703, at section 14.1, tbl. 4 (showing that 94% (VIEW1) and 95% (VIEW2) of wet AMD patients treated with three monthly 2 mg doses of aflibercept followed by 2 mg doses administered once every 8 weeks maintained visual acuity (%) (<15 letters of BCVA loss)); MYL-AFL0006405.

Regeneron contends that the commercial marketing of M710 in accordance with the prescribing information of Mylan's aBLA will induce others to use M710 in a manner that literally meets every limitation of each of the asserted claims. If for any reason Mylan asserts, and a court were to find, that a given claim limitation is not literally met, Regeneron contends that the commercial marketing of M710 in accordance with the prescribing information in Mylan's aBLA will induce others to use M710 in a manner that meets that claim limitation under

the Doctrine of Equivalents, because the manner in which Mylan and/or its customers perform that claim limitation is insubstantially different from the element as literally recited in the claims.